7/PRTS

Dry Powder Inhaler

The present invention refers to an inhaler for the uptake of medicaments in the form of dry powder and to specially designed single dose blister strips that are used with the said inhaler.

The inhaling devices currently used can be separated into two categories:

1. Those where the pharmaceutical powder is stored in a container out of which a measured amount of powder can be released via specific mechanisms. EP0069715 for example, describes a device in which the powder is metered in given dosages through apertures located in a rotatable disc, these apertures being introduced into an airduct or channel through which air is inhaled, by rotating the disc.
2. Those where measured amounts of pharmaceutical powder can be stored separately in special containers. GB2242134 for example, describes a device which uses a flexible strip defining a plurality of pockets each of which contains a dose of medicament which can be inhaled. The device contains a chamber in which the strip is housed, an opening station which contains means for peeling the two sheets or the strip apart, and an outlet through which the user can inhale the medicament.

The major disadvantages of these and other similar devices are that a. the user cannot visually verify whether he has received the entire dose of the medicament, and b. they function through complicated internal mechanisms.

The advantage of the present invention is that the user can visually check the presence of the medicament in the blister of the strip prior to inhalation and verify after the inhalation that he has received the entire dose of the medicament. Additionally, the device is simple to manufacture and easy to operate.

The device of the present invention is comprised of three parts: the mouthpiece, through which the powder is inhaled, the blister strip support surface and the strip storage compartment(s), which house(s) a large number of blister strips. The three parts are connected to each other and can be independently opened. The support surface contains an attachment point, where the blister strip is attached with the help of an attachment formation; a cavity, which accommodates the blister of the strip; and strip guides, which secure the proper and firm placement of the strip on the surface.

The single dose blister strip is comprised of two sheets that can be pealed away from each other. The base sheet has a blister which contains the powder, and an attachment formation which fits to the attachment point of the support surface. The cover sheet seals the base sheet only in the area around the blister.

The principle of use is that the user securely attaches the blister strip on the attachment surface, pulls away the cover sheet of the blister by exercising a slight force, checks the content of the blister, inhales the medicament, and finally verifies that he has received the entire dose.

Figures 1-9 depict examples of the invention.

Figure 1 shows different views of an example of an inhaler.
Figure 2 shows the mouthpiece of the device along with its component parts.

Figure 3 shows the part of the device that contains the area on which the blisters are placed.
Figure 4 shows the blister storage compartment.
Figure 5 shows a single dose blister strip and the way it is put together.
Figure 6 shows the process that reveals the powder in the blister.
Figure 7 shows the flow of air and powder during the inhalation process.
Figures 8 and 9 are further examples of inhalers based on the principle of the present invention.

The inhaler (Figure 1) includes 3 basic parts, the mouthpiece **A** with its cover, part **B** with the surface on which the blister strip is placed, and the blister strip storage part **C**. The parts are connected to each other and can be opened independently.

The mouthpiece (Figure 2) is comprised of parts **1**, **2** and **3**. Part **1** locks in part **2** and part **2** locks in part **3**.
Part **1** is the external part of the mouthpiece, and may have air openings at its base.
Part **2** is a cylinder with a wider base. The top of the cylinder has an opening **4**, which serves as the exit of the powder from the device. Inside the cylinder there is formation **5**, which may be of helical or other shape, through which the inhaled powder containing air exits the device. The end of formation **5** at the base of part **2** is blocked in half with surface **6**.
Part **3** is also a cylinder, which has a wider top. The interior of part **3** is divided in chambers **7** and **8**, by an upright flat surface **9**. The base of part **3** touches the blister. It has two holes, **10** and **11**, one on each side of dividing part **9**. Hole **11** may contain a sieve, in order to block the passage of larger particles. Chamber **7** contains hole **10**, and is blocked at its top with surface **6**. Furthermore, chamber **7** contains hole **12**, which serves as the air entrance.

The single dose blister strip is placed on the attachment surface of part **B** (Figure 3). This surface has a protrusion **13** that serves as the attachment point, a cavity **14** which receives the blister of the strip, and a system of strip guides, **15** and **16** in the specific example. The protrusion, the cavity and the guides enable the correct alignment of the strip on the surface of part **B** and secure its firm placement during the use of the device.
The lower portion of part **B** can be used as a storage compartment for the blister strips.

The strip storage part **C** (Figure 4) can be of various shapes, and may contain a grid, depending on the number of strips it accommodates, e.g. 30 or 60.

The blister strip (Figure 5) consists of two sheets (Figure 5A) made of suitable material e.g. PVC, aluminium, polyamide, paper, polyester, vinyl gum. One of the two sheets is the base sheet **17**, which has the blister **18** that contains the powder, and the attachment hole **19**. The other is the cover sheet **20** that is fixed to the base sheet, e.g. by heat adhesion, and air-tightly seals only the area around blister **18**, as shown in the drawing (Figure 5B, darkened area). Sheet **20** is then folded by a 180-degree rotation around axis **DE**, revealing hole **19** and covering the flat surface of blister **18** (Figure 5C).

The process by which the blister-contained powder is exposed takes place in two stages (Figure 6).

During the first stage (Figure 6A) and while the mouthpiece is open, the user secures the strip on the support surface of part **B** by placing hole **19** around protrusion **13**. Blister **18** is then placed in cavity **14** with the assistance of guides **15** and **16**.
During the second stage (Figure 6B), the user closes the mouthpiece and pulls cover sheet **20** towards the direction of the arrow until it is completely detached.

At this point and after lifting the mouthpiece, the user can verify that the powder contained in blister **18** has been revealed and is available for inhalation (Figure 6C). The user then just closes the mouthpiece and inhales. Finally, by opening again the mouthpiece, he can visually check whether he has inhaled the medicament.

During the process of inhalation (Figure 7) the air that is breathed-in enters the mouthpiece via the air openings, and then enters chamber **7** through hole **12**. From there on and passing through hole **10**, the air carries along the powder which is located in blister **18** and passing through hole **11** brings it to chamber **8**. From there and through formation **5**, the powder exits the device.

Another example of the invention is shown in Figure 8. The attachment point for the blister strip on surface **B** is cavity **21**. The mouthpiece **A** contains projection **22** which, when said mouthpiece is closed, enters cavity **21** and in this way secures the blister. In this case, the blister is placed on surface **B** with hole **19** above cavity **21**. Alternatively, blister strip hole **19** could be replaced by a cavity.

Figure 9 shows another embodiment of the invention. In this case, the attaching component of the blister strip is formation **23** that is placed in the openings **24** of guides **15** and **16** of surface **B**.

It is obvious that there may be variations relating to the shape and the positions of the attachment point, the cavity and the guides on surface **B**, which can achieve appropriate and secure attachment of the blister. All these different embodiments are also included in the scope of the present invention.

A further embodiment of the inhaler would include its use through the nose. This could be achieved by substituting the mouthpiece with the appropriate attachment.